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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,993	07/13/2001	Lars Nilsson	PH114205.2001/KMZ15101.02	2242

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PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS
SUITE 1600
525 WEST MONROE STREET
CHICAGO, IL 60661

EXAMINER	
PAPPU, SITA S	

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,993	NILSSON ET AL.	
	Examiner	Art Unit	
	Sita Pappu	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-28 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 12-22, 24-28, drawn to a transgenic mouse comprising a human antichymotrypsin transgene, and screening methods, classified in class 800, subclass 3.

II. Claims 11, 23, drawn to a method of treating or preventing Alzheimer's or amyloidogenic disease by administering a salt of a compound wherein the compound is a nucleic acid, classified in class 514, subclass 44.

III. Claims 11, 23, drawn to a method of treating or preventing Alzheimer's or amyloidogenic disease by administering a salt of a compound wherein the compound is a protein, classified in class 514, subclass 2+.

Claims 11 and 23 encompass the Inventions of Groups II and III. Should one of these Groups be elected, claims 11 and 23 will be examined only to the extent they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Group I is directed to a transgenic animal and methods of screening using the animal while Groups II and III are directed to gene and protein therapy respectively. The methods of Group I are materially different from those of Groups II and III. The methods of therapy of Groups II and III do not require the transgenic mouse of Group I and vice versa.

Groups II and III are distinct from each other because peptides and nucleic acids are substantially different in terms of structural, chemical, physical and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be synthesized or purified from cells. Further, the methods of Group II do not require the methods of Group III and vice versa and the dosages, modes of preparation and modes and frequency of administration are different for Groups II and III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election

Claims 8 and 9 are generic to a plurality of disclosed patentably distinct species comprising human Alzheimer's disease or amyloidogenic disease wherein the amyloidogenic disease is selected from the Group consisting of scrapie, transmissible spongioform encephalopathies (TSE's), hereditary cerebral hemorrhage with amyloidosis Icelandic type (HCHWA-I), hereditary cerebral hemorrhage with amyloidosis Dutch-type (HCHWA-D), Familial Mediterranean Fever, Familial amyloid nephropathy with urticaria and deafness (Muckle-Wells syndrome), myeloma or macroglobulinernia-associated idiopathy associated with amyloid, Familial amyloid polyneuropathy (Portuguese), Familial amyloid cardiomyopathy (Danish), Systemic

senile amyloidosis, Familial amyloid poluneuropathy (Iowa), Familial amyloidosis (Finnish), Gertsmann-Staussler-Scheinker syndrome, Medullary carcinoma of thyroid, Isolated atrial amyloid, Islets of Langerhans, Diabetes type II, and Insulinoma. These diseases or syndromes involve different etiologies, organs, disease loci and produce different symptoms. Transgenic mice that are models of the various diseases claimed would be structurally different and are thus distinct. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

S. Pappu
May 3, 2002

Anne-Marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER